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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SPIEGLER, ALEXANDER H	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/673,779	JANSEN ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☒ Claim(s) *5,7,13,17 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. This action is in response to Applicants response, filed on September 9, 2003. Currently, claims 1-22 are pending. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL, since this action contains new rejections necessitated by Applicants' amendments to the claims. Any objections and rejections not reiterated below are hereby withdrawn. Specifically, the objection to Claim 15 and the rejections of Claims 5, 7, 13, 15, 17, 19 and 23 have been withdrawn in view of Applicants amendments to the Claims. Additionally, the 102 rejection of Leong has been withdrawn in view of Applicants amendments and arguments.

Claim Objections

2. Claims 5, 7, 13, 17 and 19 recite, "selected from **a** group consisting of", which could be amended to recite, "selected from **the** group consisting of". Claim 15 recites, "a probe selected of a group composed of probes having a sequence of ...or...or...", which could be amended to recite, "a probe selected from the group consisting of SEQ ID NO: 5, SEQ ID NO: 6, and SEQ ID NO: 7".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 14 over "said nucleic acid" because this recitation lacks antecedent basis.

Applicants have not amended the claims or provided an argument for this rejection. Accordingly, the rejection is maintained.

Written Description

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 7, 15, 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

35 U.S.C.§ 112, requires, *inter alia*, that a patent specification contain a written description of the invention and the manner and process of making and using it "...in such full clear and concise terms as to enable one skilled in the art... to make and use" the invention. While it is well settled that a patent application need not teach each possible embodiment of the claimed invention, it is manifestly true that written description cannot be settled by reliance on that which has not been achieved in the art, or that which is not disclosed in the specification. That is, a specification is not considered to satisfy the requirement for an adequate written description if it fails to disclose the specific starting materials or conditions for making the

invention. (*Genentech, Inc. v. Novo Nordisk*, 108 F3d. 1361, 42 USPQ2d 100. Fed. Cir. 1997), or evidence that the applicants at the time the application was filed, has possession of the claimed invention.

Additionally, *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed* (See page 1117)." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (See *Vas-Cath* at page 1116)."

Applicant's attention is also drawn to the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1st Paragraph, Written Description Requirement" (published in Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111).

> Possession may be shown in many ways. For example, possession may be shown, *inter alia,* by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas, which permit a person skilled in the art to clearly recognize, that applicant had possession of the claimed invention. *An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention...*
>
> Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient..for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession.

(pgs. 1105-1106).

In the instant case, Claims 7, 15, 19 and 21 are all drawn to probes comprising "no more than five mismatches" with probes selected from SEQ ID NOS: 1-12. These claims encompasses a plurality of possible probes, wherein the specification does not set forth any description of sufficient, relevant, identifying characteristics of these claimed probes so that a person skilled in the art would recognize that the inventor had possession of the claimed invention. First, claims 15 and 19 recite, "having", which suggests that the probes could comprise larger sequences than the probes (i.e. SEQ ID NOS: 1-12) recited in the claims. The specification does not teach any probes that are larger than the recited probes (i.e., SEQ ID NOS: 1-12), or any sufficient, relevant, identifying characteristics of larger probes. Furthermore, claims 7, 15, 19 and 21 recite, "no more than five mismatches", which suggests that there could be one to five mismatches in any of recited probes (i.e., SEQ ID NOS: 1-12). The specification does not set forth any description of sufficient, relevant, identifying characteristics of the plurality of possible probes encompassed by the claimed invention, so that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Applicant has only taught 12 specific probes of the claimed invention (see pg. 13 of the specification).

Accordingly, there is not an adequate written description for the claimed invention.

Applicants Arguments

Applicants argue, "In large part, it would appear the Examiner is objecting to the use of 'capable of'. Applicant has amended the claims to delete this term" (see Applicants remarks on Page 6).

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive. While Applicants' amendments have overcome the written description rejection, in part (i.e., part of rejection relating to "capable of"), Applicants' have not overcome the rejection with respect to the recitation of "no more than five mismatches" (see above). Accordingly, the rejection is maintained.

Scope of Enablement

7. Claims 7, 15, 19 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NOS: 1-12, does not reasonably provide enablement for probes comprising "no more than five mismatches". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Case law has established that "(t)o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *In re Wright* 990 F.2d 1557, 1561. In *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) it was determined that "(t)he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art". The amount of guidance needed to enable the invention is related to the amount of knowledge in the art as well as the predictability in the art. Furthermore, the court in *Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001 held that "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement".

Also, MPEP 2164.01 states:

"Even though the statute does not use the term 'undue experimentation,' it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)."

The *Wands* court outlined several factors to be considered in determining whether a disclosure would require undue experimentation:

> "They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

Id. at 1404.

In the instant case, the specification does not enable one of skill in the art to make and use the claimed invention for the following reasons:

(1) The quantity of experimentation necessary

In order to practice the invention, the practitioner must experiment by creating one to five mismatches in SEQ ID NOS: 1-12, wherein the probes comprising said mismatches can be used in an "*in situ* hybridization protocol selected on the basis of whether the Gram-staining indicated the presence of a Gram-negative or Gram-positive staining". While a skilled artisan may be able create mutations in nucleic acid probes, the likelihood that the mutated probes could be used in the claimed methods is highly unpredictable, and can only be tested by carrying out the complete claimed method. In essence, the experimentation that one skilled in the art would be required to perform is in fact the proposed novelty of the invention. "(I)t is the specification, not the knowledge of one skilled in the art that must supply the novel aspects of the invention in order to constitute adequate enablement". (*Genetech Inc. v Novo Nordisk* 42 USPQ2d 1001).

Therefore, the quantity of experimentation is not only difficult, but also unpredictable.

(2) The amount of direction or guidance presented

The specification teaches that the probes of SEQ ID NOS: 1-12 are capable of carrying out the claimed methods (see pgs. 13, 17 and 19-20). However, the specification does not provide any direction or guidance in making or using probes having "no more than five mismatches" and still function in the claimed invention.

(3) The presence or absence of working examples

The only working examples use the probes of SEQ ID NOS: 1-12 (see pgs. 16-21). However, there are no working examples of making or using probes having "no more than five mismatches" and still function in the claimed invention.

(4) The nature of the invention

The nature of the invention pertains to the detection of bacteria in samples using nucleic acid probes.

(5) The state of the prior art

The prior art of Leong et al. (EP 0479117, cited in the IDS) teaches that specific nucleic acid probes can be used for bacteria detection using in *situ* hybridization protocols (see pgs. 7-10).

(6) The relative skill of those in the art

The level of skill in molecular biology is high, as one of ordinary skill in the art would have to experiment by creating one to five mismatches in SEQ ID NOS: 1-12. Once the skilled artisan had obtained said probes, he would have to experiment to determine whether the probes comprising said mismatches can be used in an "*in situ* hybridization protocol selected on the

basis of whether the Gram-staining indicated the presence of a Gram-negative or Gram-positive staining".

(7) The predictability or unpredictability of the art

The unpredictability of finding mismatches in SEQ ID NOS: 1-12, which can be used in the claimed invention, is high, since the specification or state of the art teaches any specific criteria in selecting mutations in SEQ ID NOS: 1-12 that can be used in the claimed method. The experimentation in finding probes of the claimed invention (comprising said mismatches) would be unpredictable, since the process of finding probes that can be used in the claimed invention would require a random trial and error process, with little to no starting point.

(8) The breadth of the claims

The invention is directed to a method for identifying the presence of a bacterium in a sample comprising testing said sample by Gram-staining and testing said sample with a probe according to an *in situ* hybridization protocol selected on the basis of whether the Gram-staining indicated the presence of a Gram-negative or Gram-positive staining and indentifying the presence of the bacterium in the sample.

Accordingly, in view of the unpredictability in the art and in view of the lack of specific disclosure in the specification, undue experimentation would be required to practice the invention as it is claimed.

Applicants are reminded that the enablement requirement of 35 U.S.C. 112, first paragraph, is separate and distinct from the description requirement. Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991).

Applicants Arguments

Applicants argue, "Again, the rejection appears to hinge on the use of the term "capable of". (see Applicants remarks on page 6). Applicants have amended the claims to delete "capable of".

Response to Applicants Arguments

Applicants' arguments have been considered, but are not persuasive. While Applicants' amendments have overcome the enablement rejection, in part (i.e., part of rejection relating to "capable of"), Applicants' have not overcome the rejection with respect to the recitation of "no more than five mismatches" (see above). Accordingly, the rejection is maintained.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 2, 4, 6, 20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyldig-Nielsen et al. (USPN 5,888,733).

Nielsen teaches a method for identifying the presence of a gram negative, cocci bacterium (*Neisseria gonorrhea*) in a sample comprising testing said sample by Gram-staining and testing said sample with a probe according to an *in situ* hybridization protocol selected on the basis of whether the Gram-staining indicated the presence of a Gram-negative or Gram-positive staining and identifying the presence of the bacterium in the sample (col. 29, Example

14). The reference teaches the sample is a clinical sample and the nucleic acid is ribosomal RNA (col. 29, Example 14).

Applicants Arguments

Applicants argue:

> The referred to example 14 in column 29 of '733 does not explicitly state that it uses Gram-staining. The example mentions that samples were evaluated as positive on the basis of methylene blue staining and/or Gram-staining....Moreover, if a Gram-staining procedure was performed prior to the hybridization, '733 still does not disclose the present invention. In the present invention, the hybridization protocol, including the choice of probe to use, is dependant on whether the Gram-staining indicates the presence of a Gram-negative or Gram-positive bacterium. In '733 methylene blue and/or Gram-staining is used to determine whether the sample is positive or not, i.e., only to determine whether the sample contains bacteria....The hybridization protocol is not selected on the basis on the outcome of the staining. The hybridization protocol is fixed...There is no alternative hybridization protocol disclosed that is used based on the outcome of the Gram-staining.

Response to Applicants' Arguments

Applicants arguments have been considered, but are not persuasive for the following reasons. First, as Applicants' point out, '733 states, "the samples were evaluated as positive on the basis of methylene blue *and/or Gram staining*" (emphasis added). This means that Gram-staining was either used alone or in conjunction with methylene blue staining, but regardless, Gram-staining was carried out. Next, '733 teaches that a positive reading was found in the gram-stain. Applicants interpret positive results of the Gram-stain to only determine whether or not the sample contains bacteria. However, a gram-stain may not be performed simply to determine whether or not a sample contains bacteria, but what type of bacteria is present. Specifically, the specification states, "four types of bacteria are found after Gram-staining; Gram-negative rods and cocci and Gram-positive rods and cocci". (See page 1, paragraph 3). Therefore, in the present case, when '733 states the samples were "positive", it would have to mean that the result

from the gram-stain was that the sample contained gram-negative cocci bacteria, which is the type of bacteria N. gonorrhea is. It is based on this result of the gram-staining that '733 teaches hybridizing probes to the sample (i.e., testing said sample with a probe according to an *in situ* hybridization protocol selected on the basis of the outcome of whether the Gram-staining indicates a Gram-negative staining). That is, if the gram-staining turned out to be "negative", and not gram-negative cocci bacteria (e.g., a gram-positive rod bacteria), the probes would not have been hybridized to the sample, but because the gram-staining was "positive", and therefore, a gram-negative cocci bacteria, the probes were hybridized to the sample. Applicants arguments as to "alternative hybridization protocols" is not persuasive, since the probes in '733 were hybridized based on the outcome of the gram-staining to be "positive" or gram-negative cocci bacteria.

Accordingly, the rejection is maintained.

10. Claims 1, 2, 4, 9, 11, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hashimoto et al. (EP 0326989).

Hashimoto teaches a method for identifying the presence of a bacterium in a sample comprising testing said sample by Gram-staining and testing said sample with a probe according to an *in situ* hybridization protocol selected on the basis of whether the Gram-staining indicated the presence of a Gram-negative or Gram-positive staining and identifying the presence of the bacterium in the sample (pages 2-3, Examples 2-3). Hashimoto teaches the sample is a clinical sample (see Examples 2-3 and page 2, lines 49-52), the gram-staining indicates the presence of gram-negative rod bacteria, as well as, gram-positive coccus bacteria, streptococcus pneumoniae, (see Examples 2-3).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 3, 5 and 7-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyldig-Nielsen et al. (USPN 5,888,733) as applied to claims 1, 2, 4, 6, 20 and 22 above, and further in view of Leong et al. (EP 0479117, cited in the IDS).

Nielsen teaches a method for identifying the presence of a gram negative, cocci bacterium (*Neisseria gonorrhea*) in a sample comprising testing said sample by Gram-staining and testing said sample with a probe according to an *in situ* hybridization protocol selected on the basis of whether the Gram-staining indicated the presence of a Gram-negative or Gram-positive staining and identifying the presence of the bacterium in the sample (col. 29, Example 14). Nielsen does not teach methods for identifying gram-positive bacteria or specific types of gram-negative bacteria.

However, identifying both gram-positive and specific types of gram-negative bacteria are well known in the art. For example, Leong teaches the identification of both gram-positive and gram-negative bacteria in order to identify and/or treat septicemia (pg. 2). Leong also teaches probes comprising no more than 5 mismatches for SEQ ID NOS: 1-12 (see pages 19-23).

Therefore, in view of the teachings of Leong, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to have modified Nielsen's method of performing a gram-staining test on a sample, and then testing said sample with a probe according to an *in situ* hybridization test, selected on the basis on said gram-staining test, so as to have included the steps of performing the above method on a wide array of bacteria (including gram-positive bacteria, and gram-negative bacteria, such as E. *aerogenes*), in order to have achieved the benefit of providing an effective means of identifying bacteria for use in treatment of conditions caused by septicemia.

13. Claims 3, 5-8, 10, 12-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al. (EP 0326989), as applied to claims 1, 2, 4, 9, 11, and 20 above, and further in view of Leong et al. (EP 0479117, cited in the IDS).

Hashimoto teaches a method for identifying the presence of a bacterium in a sample comprising testing said sample by Gram-staining and testing said sample with a probe according to an *in situ* hybridization protocol selected on the basis of whether the Gram-staining indicated the presence of a Gram-negative or Gram-positive staining and identifying the presence of the bacterium in the sample (pages 2-3, Examples 2-3). Hashimoto does not teach methods for identifying gram-positive bacteria or specific types of gram-negative bacteria.

However, identifying both gram-positive and specific types of gram-negative bacteria are well known in the art. For example, Leong teaches the identification of both gram-positive and gram-negative bacteria in order to identify and/or treat septicemia (pg. 2). Leong also teaches probes comprising no more than 5 mismatches for SEQ ID NOS: 1-12 (see pages 19-23).

Therefore, in view of the teachings of Leong, it would have been obvious to one of

ordinary skill in the art at the time the invention was made to have modified Hashimoto's method of performing a gram-staining test on a sample, and then testing said sample with a probe according to an *in situ* hybridization test, selected on the basis on said gram-staining test, so as to have included the steps of performing the above method on a wide array of bacteria (including gram-positive bacteria, and gram-negative bacteria, such as E. *aerogenes*), in order to have achieved the benefit of providing an effective means of identifying bacteria for use in treatment of conditions caused by septicemia.

Conclusion

14. No claims are allowable. Probes **consisting of** SEQ ID NOS: 1-3, 5-8 and 10 are free of the prior art.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Welling et al. (GenEmbl Accession No. A59320), teaching the probe consisting of SEQ ID NO: 4.

Nippon Seifun (N_Geneseq Accession No. Q88892), teaching the probe consisting of SEQ ID NO: 9.

Rider, J. (GenEmbl Accession No. A58315), teaching the probe consisting of SEQ ID NOS: 11-12.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806 or (571) 272-0788 after January 22, 2004. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119 or at (571) 272-0782 after January 22, 2004. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
January 2, 2004

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600